



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,237	10/19/2000	David S. Wells	085747/0170	5026

22428 7590 11/05/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,237

Applicant(s)

WELLS ET AL.

Examiner

Lakshmi S Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,37-42,44-55 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,37-42,44-55 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1615

DETAILED ACTION

Receipt of amendment and remarks dated 3-01-2004 is acknowledged.

Claims 35, 37-42, 44-55 and 57 are pending.

Response to Arguments

Applicant's arguments with respect to claims 35, 37-42, 44-55 and 57 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Claims 35, 37-39, 41, 42, 47, 51-54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,571,333 to Hsiao in view of WO 99/44623 or WO in view of Hsiao.

Hsiao teaches sustained release formulations comprising naproxen and naproxen salts in the form of oral tablets suitable for once-daily administration. The naproxen composition of Hsiao is made of a matrix composition 81-96% % by weight of naproxen and 4-9% by weight of hydroxypropyl methylcellulose and other excipients (examples, col. 4, lines 59-68 and col. 5, lines 1-4). Hsiao does not teach the claimed active agents.

WO teaches compositions comprising valerian extracts, isovaleric acid and their derivatives in combination with non-steroidal anti-inflammatory compounds such as naproxen, ibuprofen etc (page 14-page 17). Isovaleric acid and other valerian extracts taught by WO read on the instant claimed active agents. WO further teaches that the oral isovaleramide or valerian extract containing compositions, together with anti-inflammatory compounds can be prepared in the form of enteric-coated tablets, capsules etc., so as to successfully treat muscular aches, pain, as well as inflammation. WO fails to teach a gelling agent or matrix formulation for the above

Art Unit: 1615

active agents. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the composition of WO containing isovaleramide, isovaleric acid or valerian extracts and anti-inflammatory agents such as naproxen in the form of an oral sustained release matrix by adding a sustained release swelling agent, HPMC, because Hsiao teaches that the pain or inflammation treating composition prepared in a matrix with HPMC prolongs the release of the active agent so as to achieve a once-a-day administration. Alternatively, it would have been obvious for a skilled artisan at the time of the instant invention to add valerian extracts, isovaleramide etc. to the anti-inflammatory naproxen containing composition of Hsiao because WO suggests that the combination treats inflammation as well as provides a relief from acute pain and muscular tension. With respect to the claimed weight percentage, WO teaches upto 600 mg of active ingredient per tablet and further, the percentages of active ingredient and HPMC taught by Hsiao are within the claimed ranges. With respect to the process of preparing the composition, Hsiao teaches the same steps of mixing the ingredients, extruding and compressing to form tablets (col. 7). Accordingly, optimizing the amount of drug and the release agent, as well as choosing an appropriate release agent so as to achieve the desired release rate are within the scope of a skilled artisan.

Claims 40, 44-46, 48-50, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,571,333 to Hsiao in view of WO 99/44623 or WO in view of Hsiao as applied to claims 35, 37-39, 41, 47, 51-54 and 57 and further in view of Groshovy et al (Groshovy, submitted on PTO-1449).

Art Unit: 1615

Hsiao and WO, discussed above, fail to teach a film coating that retards the access of the liquids to the active compounds.

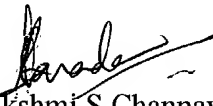
Groshovy teaches coating of tablets with intestine soluble film forming polymer such as acetylphthalylcellulose so as to enhance the physical strength and resistance to the action of gastric juice (page 1). Groshovy teaches tablets containing valerian extracts are usually destroyed by gastric juices in two hours and the resulting weight loss prompts the addition of plasticizers to the film-forming substances (page 4). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ a film-forming coat over the oral composition of WO containing valerian extracts and anti-inflammatory such as naproxen in the form of a sustained release matrix containing HPMC (the sustained release agent of Hsiao) because Groshovy teaches that tablets containing valerian extracts are sensitive to gastric juices and a film-forming polymer together with a plasticizer reduces the sensitivity of the composition to gastric juices and the plasticizer enhances the strength of the film surrounding the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
November 4, 2004